REMARKS/ARGUMENTS

Claims 1, 7-40, 76-79 and 82 are pending in this application. The Applicant thanks the Examiner for their careful consideration of the present application and their withdrawal of the previous rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 103(a)

In the Final Office Action mailed April 1, 2009, the Examiner rejected claims 1, 7-40, 76-70, and 82 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,022,316 (hereinafter, "the '316 patent") in view of U.S. Patent No. 6,692,456 (hereinafter, "the '456 patent"). Applicants respectfully traverse the rejection.

The Examiner states that the '316 patent discloses a method of delivering drugs through and/or withdrawing fluids from a biological membrane comprising the steps of applying at least one heated probe element capable of delivering thermal energy to cause ablation of the membrane to form a plurality of openings wherein the depth of the micropores preferably ranges from 40-180 microns. The Examiner acknowledges that the '316 patent does not specifically teach an opening depth of the majority of the delivering openings falls within a range of about 40 to about 90 microns or that the delivery openings have a distribution resulting in a bell-shaped curve with the delivery openings having a mean opening depth of between about 40 and 90 microns. However, the Examiner argues that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the openings with the recited distribution, since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, citing *In re Aller*, 105 USPQ 233 (CCPA 1995), on page 3, last paragraph of the Office Action.

Applicants respectfully submit the general conditions of the currently pending claims are not disclosed in the '316 patent. The '316 patent is directed to "creating an electroporation effect to selectively enhance the permeability of selected structures within a tissue (Column 3, lines 63-67). The range of micropore depths recited by the '316 patent are for the purposes of electrically coupling a first and second electrode to the micropores (Column 4, line 66 - Column 5, line 25). An electric voltage pulse or series of pulses is then applied resulting in permeability enhanced tissue from which fluid may be collected, or a substance may be delivered to (Column 5, lines 26-59). Thus, the '316 patent establishes a workable range of micropore depth for use in

electroporating tissue, but does not establish a workable range for delivery of a substance without electroporation, i.e., the present invention. As noted in the present application, traditional transdermal delivery literature suggests that to produce a dramatic increase in flux of any permeant, the depth of the delivery opening need only be past the thickness of the stratum corneum (15-30 microns thick (page 24, last paragraph). The '316 patent only suggest extending past this range when electroporation is involved. Moreover, the '316 patent teaches away from the present invention by indicating that formation of micropores itself is not sufficient for delivery of a permeant, but instead needs to be coupled with electroporation to achieve effective delivery via increased tissue permeability. In other words, there is no reasonable expectation provided by the '316 patent that extending the micropore depth beyond 15-30 microns would result in an optimum depth for delivery of a permeant without the concomitant use of electroporation. The prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 721 F.2d 1540, 220 USPQ 3030 (Fed. Cir. 1983).

The Examiner notes that the '316 patent does not recite the use of a delivery patch. The Examiner alleges that '456 patent discloses a method of delivering drugs through created micropores by placing a patch on the openings. Therefore, the Examiner alleges it would have been obvious to one of skill in the art to modify the method of the '316 patent to include a step of patch drug delivery as disclosed by the '456 patent. The disclosure of the '456 patent does not remedy the deficiencies of the '316 patent noted above. Given that the present rejection depends on the combined teachings of the '316 patent and the '456 patent, the Examiner's arguments regarding the '456 patent are rendered moot.

For at least the foregoing, Applicants submit the rejection under 35 U.S.C. § 103(a) has been overcome and respectfully request that it be withdrawn.

CONCLUSION

The foregoing is submitted as a full and complete response to the Final Office Action mailed April 1, 2009, and early and favorable consideration of the claims is requested. If the Examiner believes any informalities remain in the application that may be corrected by

Examiner's amendment, or there are any other issues which can be resolved by telephone interview, please call the undersigned agent at (404) 572-2447.

Applicants submit that no additional fees are required for submission of this paper. However, the Commissioner is hereby authorized to charge any fee deemed necessary for consideration of this paper, and to credit any overpayment, to Deposit Account No. 11-0980.

Respectfully submitted,

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